

REMARKS

This communication is in response to the final Office Action mailed June 11, 2008. A Request for Continued Examination is submitted herewith so that the Communication may be considered by the Examiner in the instant case.

Claims 1-23, 25-35 and 37-46 were pending in the application. Of those, claims 1, 3, 4, 8, 29, and 33 have been amended; claims 2, and 6-7 have been cancelled; and claims 3-5 and 14-22 remain withdrawn.

The withdrawn claims 3 and 4 have been amended to depend from claim 1, rather than the cancelled claim 2 to perverse the right to rejoinder. Claim 29 has been amended to correct clerical errors. Claims 1 and 33 have been amended to recite that a surfactant is an optional ingredient and that "the dispersion of tensioning polymer particles comprise at least one polymer selected from the group consisting of (1) polyurethane and polyacrylic polymers in the form of interpenetrated networks, (2) polyurethane polymers, (3) sulphonated isophthalic acid polymers, and (4) grafted silicone polymers having a main silicone chain." Support for this amendment can be found throughout the specification including, for example, the cancelled original claims 2, 6 and 7; paragraphs [0009] and [0010] on page 3; and paragraph [0023] on page 5 of the originally filed specification. Accordingly no new matter has been introduced by these amendments.

Rejection based on 35 U.S.C. § 112

The Examiner has rejected claims 8-13 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Examiner has alleged that "[i]t is unclear how the polymers of claims 8-10 are ionic when the requirement is for the amphiphilic polymer to be ionic" since of the recited polymer, AMPS is anionic, and some other polymers also do not appear to be ionic. The

Examiner has also alleged that the boundaries of AMPS derivatives in claim 8 are not defined, and has requested the specific recitation of what the "AMPS" stands for followed by parenthetical expression of the "AMPS" to eliminate ambiguity of the abbreviated term. Applicant respectfully traverses these grounds of rejection.

The test for definiteness under 35 U.S.C. § 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 U.S.P.Q.2d 1081, 1088 (Fed. Cir. 1986). If one skilled in the art is able to ascertain the meaning of the terms, for example, "ionic amphiphilic polymer" and "AMPS derivatives" in light of the specification, 35 U.S.C. § 112, second paragraph, the test is satisfied.

The detailed description of the application describes "ionic amphiphilic polymers" as follows:

As indicated above, the composition according to the invention also contains an **ionic amphiphilic polymer**.

This expression means **cationic, anionic** or **amphoteric** polymers comprising both a hydrophilic portion and a hydrophobic portion and having the property of forming a film that separates two liquids of different polarity, thus making it possible to stabilize liquid-liquid dispersions of direct, inverse or multiple type. More specifically, the amphiphilic polymers according to the invention have the property of reducing the water/oil interface tension to 10mN/m, irrespective of the oil.

See page 7, [0033] & [0034] of the original specification (emphasis added).

The specification goes on to define each of the specifically recited ionic amphiphilic polymers, i.e., acrylic

copolymers, hydrophobic AMPS derivatives, acrylic terpolymers or sulphoisophthalic copolyesters in pages 8-19. The section describing the AMPS derivative is in pages 11-14.

Based on the detailed description in the present specification of these terms, those skilled in the art could interpret the metes and bounds of the claim when the claim is read in light of the specification. Thus, applicant submits that the terms "ionic amphiphilic polymers" and "AMPS derivatives" are not indefinite.

Moreover, according to the very prior art reference the Examiner has cited to support the obviousness rejection in the present Office Action, i.e., *Dubief et al.* (U.S. Patent No. 6,090,376) ("*Dubief*"), also uses the term "ionic amphiphilic polymer."

In addition, claim 8 has been amended to include the specific recitation of what "AMPS" stands for as follows:

8. (currently amended) The composition of claim 1, wherein said ionic amphiphilic polymer is selected from acrylic copolymers, hydrophobic 2-acrylamido-2-methylpropane sulphonic (AMPS) acid derivatives, acrylic terpolymers or sulphoisophthalic copolyesters.

Therefore, applicant respectfully requests that the rejection based on 35 U.S.C. § 112, second paragraph be withdrawn.

Rejection based on 35 U.S.C. § 103(a)

The Examiner has rejected claims 1, 2, 6-13, 23, 25-35 and 37-42 under 35 U.S.C. § 103(a) as being unpatentable over *Dubief*.

The Examiner has alleged that *Dubief* discloses a composition comprising at least one grafted silicone polymer in particles dispersed in aqueous medium, amphiphilic polymer, water, vegetable animal or synthetic oils or vitamins or

surfactants. The Examiner has alleged that the difference between the prior art and the claimed invention is in the % amount of the surfactant, but because *Dubief* generally teaches that an amount of 0-20% of surfactant can be present relative to the total weight of the composition, based on routine optimization, one of ordinary skill in the art would have arrived at the present invention. Applicant respectfully traverses because *Dubief* fails to teach all of the elements of the present invention, and also fails to provide any rationale/motivation to arrive at the claimed invention.

To establish a *prima facie* case of obviousness under Section 103, the references relied upon for rejection must suggest the entirety of the claimed invention and, hence, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

All of the independent claims pending in the application, i.e., claims 1 and 33, as amended, recite that the **grafted silicone polymers** have a **main silicone chain**. *Dubief*, however, fails to teach the use of such grafted silicone polymers.

More specifically, the first paragraph of *Dubief* states:

The present invention relates to a cosmetic or dermatological composition for the treatment of keratinous substances, particularly human hair, comprising at least one grafted silicone polymer with a **non-silicone organic skeleton** grafted by monomers containing a polysiloxane and at least one ionic amphiphilic polymer containing at least one fatty chain and at least one hydrophilic unit.

Dubief, col.1 ll.6-12.

Moreover, *Dubief* further states:

The inventors have surprisingly discovered that the use of an ionic amphiphilic polymer containing at least one fatty chain and at least one hydrophilic unit as thickening agent in hair compositions containing a polymer with a **non-silicone organic skeleton** grafted by monomers containing a polysiloxane made it possible not only to increase the viscosity of the medium of these compositions but also to improve, on application, the deposition of the grafted silicone polymer.

Dubief, col.1, 11.32-44 (emphasis added).

Accordingly, the invention disclosed in *Dubief* is the combination of two specific ingredients: (1) an ionic amphiphilic polymer and (2) a thickening agent containing a polymer with a **non-silicone organic skeleton** grafted by monomers containing a polysiloxane. The only independent claim in *Dubief*, i.e., claim 1, also recites a composition comprising these two ingredients as claim limitations.

Based on this very specific discovery taught in *Dubief*, one of ordinary skill in the art would not be motivated to substitute the thickening agent of *Dubief* as a tensioning polymer in the present invention. See *Life Techs. Inc. v. Clontech Lab., Inc.*, 224 F.3d 1320, 1325, 56 U.S.P.Q.2d 1186, 1190 (Fed. Cir. 2000) (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454, 227 U.S.P.Q. 293, 297 (Fed. Cir. 1985)) (which notes that the person of ordinary skill is an objective legal construct presumed to think along conventional lines without undertaking to innovate, whether by systematic research or by extraordinary insights).

In *Life Techs.*, the Federal Circuit reiterated its statements in *Standard Oil* as follows:

Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system,

possess something - call it what you will - which sets them apart from the workers of ordinary skill, and one should not go about determining obviousness under § 103 by inquiring into what patentees . . . would have known or would likely have done, faced with the revelations of references.

Id.

In fact, if one were to arrive at the present invention based on *Dubief*, the critical component of *Dubief*, i.e., a polymer with a *non-silicone organic skeleton* grafted by monomers containing a polysiloxane, must be removed from the composition, thereby destroying the operability of the composition for its disclosed purpose. A modification of references that destroys the operability of the references is not obvious. See *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (reversing the decision of obviousness on the ground that the proposed modification of the prior art would have rendered the claimed invention inoperable for its intended purpose).

Since *Dubief* not only fails to disclose all of the elements as claimed in the pending application, but also fails to provide any rationale to arrive at the claimed invention without destroying the operability of the cited reference, the Examiner fails to establish a *prima facie* case of obviousness, and therefore Applicant respectfully requests withdrawal of the obviousness rejection based on *Dubief*.

With respect to the Examiner's allegation that the amount of surfactant recited in the claims is a result of mere routine optimization within the technical skill of ordinary skill in the art, Applicant submits that the evidence of unexpected results of record disclosed in the present specification clearly weighs in favor of a contrary conclusion.

As illustrated in Table 1 and the explanation of the results in pages 28-29 of the present specification provided

below, replacing all or partial amounts of the surfactants with an ionic amphiphilic polymer provides unexpected results:

TABLE 1

<u>Retraction of isolated stratum corneum</u>	
Compositions	% of retraction of a sample of isolated stratum corneum
Example 1: O/W direct emulsion containing 7% Avalure UR410 (surfactant content: 3.5%)	0.57% \pm 0.26
Example 2: O/W direct emulsion containing 6% Avalure UR410 (surfactant content: 0.8%)	1.56% \pm 0.31
Example 3: W/O/W multiple emulsion containing 6% Avalure UR410 (surfactant content: 0.8%)	1.50% \pm 0.35
Example 4: O/W emulsion containing 7% Avalure UR410 (no surfactant)	2.76% \pm 0.77

[0130] As is seen from this table, the tensioning effect of a surfactant-rich O/W emulsion containing 7% Avalure UR 410 is not significant (Comparative Example 1). In contrast, the O/W and W/O/W emulsions according to the invention (Examples 2 to 4) containing 6% or 7% Avalure UR410 and less than 1% surfactant produce a tensioning effect, making it possible to envisage their use for restoring the tautness of the skin and smoothing out wrinkles and fine lines.

Example 1 in Table 1 is a comparative formulation containing a tensioning polymer, ionic amphiphilic polymer and 3.5% of surfactant. Examples 2-4 are the inventive formulations containing either none or less than 1% of surfactant. The results clearly show that when either none or less than 1% of surfactant is present in the formulation along with a tensioning polymer and an ionic amphiphilic polymer, more than 100%, and in some cases, more than 400% of improvement in tensioning effect was measured compared to the comparative example containing 3.5% of surfactant.

These test results clearly demonstrate that using the recited amount of surfactant in the presently pending claims

(that is either none or less than 1% surfactant) provides quite unexpected results in producing the tensioning effect.

The record does not reflect that this evidence has been considered in the obviousness determination. The rejection does not address this evidence or put forth any reasoning as to why the unexpected results presented in the specification are not sufficient to overcome a *prima facie* case of obviousness. The M.P.E.P., however, is clear as to how such evidence is to be treated. Objective evidence of secondary considerations, e.g., unexpected results, is relevant to the issue of obviousness, and regardless of whether it is presented in the specification, by counsel or via affidavit or declaration, must be considered in every case in which it is present, and that when evidence of any such secondary consideration is submitted, the Examiner must evaluate the evidence. (See M.P.E.P. § 2145 (8th Ed., Rev. 6, August 2007 at 2100-162 - 2100-163) (citing *In re Soni*, 54 F.3d 746, 750, 34 U.S.P.Q.2d 1684, 1687 (Fed. Cir. 1996)) (error not to consider evidence presented in the specification).

Accordingly, while Applicant submits that *Dubief* fails to establish a *prima facie* case of obviousness, even if that were not the case, the evidence of unexpected results clearly weigh in favor of a contrary conclusion, and therefore Applicant respectfully requests withdrawal of the obviousness rejection based on *Dubief*.

The Examiner has also rejected claims 1, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over *Dubief* in view of *Nandagiri et al.* (U.S. Patent No. 5,362,486) ("*Nandagiri*").

The Examiner has alleged that although *Dubief* "does not teach polyurethane and polyacrylic polymers as tensioning polymer as recited in claim 7," the secondary reference, *Nandagiri*, discloses a composition comprising polyurethane-acrylate, which forms in-situ when applied to hair, and therefore it would have been obvious to one of ordinary skill in

the art to use the polymer formed in-situ of *Nandagiri* in the composition of *Dubief*.

Applicant respectfully traverses because the Examiner has failed to make a *prima facie* case of obviousness since (1) there is no motivation to combine *Dubief* with *Nandagiri* to arrive at the claimed invention, and (2) the combination of *Dubief* and *Nandagiri* fails to teach all of the claimed elements.

First, as mentioned above, the primary reference, *Dubief*, teaches the use of two specific ingredients, i.e., (1) an ionic amphiphilic polymer and (2) a polymer with a **non-silicone organic skeleton** grafted by monomers containing a polysiloxane as a thickening agent to increase the viscosity of the medium of these compositions but also to improve, on application, the deposition of the grafted silicone polymer. *Dubief*, col.1 ll.32-44 (emphasis added).

The secondary reference, *Nandagiri* discloses a composition suitable for treatment of hair comprising polymerizable oligomers/prepolymers, such as reactive urethanes and urethane-acrylate oligomers. The oligomers are polymerized in-situ, e.g., with a thermal appliance, such as a blow dryer or a curling iron, and/or by including a polymerization accelerator or polymerization catalyst in the composition or in a separate composition. (col.3 ll.40-54).

Accordingly, if one were to combine *Dubief* and *Nandagiri*, the polymer with a **non-silicone organic skeleton** of *Dubief* would be replaced by *Nandagiri*'s polymerizable oligomers/prepolymers or the polymers formed thereof in-situ, thereby destroying the operability of the composition taught in *Dubief*. Such a modification, however, is not obvious. See *In re Gordon*.

Moreover, neither *Dubief* nor *Nandagiri* discloses the term "tensioning polymer" anywhere in the document and also fails to disclose or teach polyurethane, polyacrylate, or

grafted silicone polymer having main silicon chain/skeleton which possesses the tensioning qualities as defined in the present application. Simply, just because something is a polyurethane or polyacrylate does not mean that it has tensioning properties as defined in the present application. Accordingly, the combination of *Dubief* and *Nandagiri* fails to disclose all of the elements as claimed in the pending application.

Furthermore, Applicant submits that the collected teachings of the cited references, *Dubief* and *Nandigiri*, do not suggest the evidence of unexpected results of tensioning effect described in the specification in Table 1. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Finally, the Examiner has rejected claims 1 and 43-46 under 35 U.S.C. § 103(a) as being unpatentable over *Dubief* in view of *Dalko et al.* (U.S. Patent No. 6,846,812) ("*Dalko*").

The Examiner has alleged that although *Dubief* does not teach using the composition containing a grafted silicone polymer to treat/smooth wrinkled skin or restore skin tautness, the secondary reference, *Dalko*, discloses that grafted silicone has the capability of fading out irregularities in the skin such as wrinkles and fine lines. Therefore, the Examiner has concluded that it would have been obvious to one of ordinary skill in the art to apply the composition of *Dubief* to the skin as taught in *Dalko*.

Applicant respectfully traverses because the Examiner has failed to make a *prima facie* case of obviousness since there is no motivation to combine *Dubief* with *Dalko* to arrive at the claimed invention.

Dalko focuses on the novel 7-oxo-DHEA derivative, which can be used to treat signs of aging of the skin, and a cosmetic composition comprising same. *Dalko* also discloses that the composition comprising the novel 7-oxo-DHEA derivative can

include at least one other active agent, such as a tensioning agent. (col.6 ll.14-28; col.10 ll.60-62; col.11 ll.29-45; col.12 ll.50-53).

As mentioned above, the primary reference, *Dubief*, teaches the use of two specific ingredients, i.e., (1) an ionic amphiphilic polymer and (2) a polymer with a ***non-silicone organic skeleton*** grafted by monomers containing a polysiloxane as a thickening agent to increase the viscosity of the medium of these compositions but also to improve, on application, the deposition of the grafted silicone polymer. *Dubief*, col.1 ll.32-44 (emphasis added).

Accordingly, if one were to combine *Dubief* and *Dalko*, the polymer with a ***non-silicone organic skeleton*** of *Dubief* would be replaced by *Dalko*'s tensioning agents, thereby destroying the operability of the composition taught in *Dubief*. Such a modification, however, is not obvious. See *In re Gordon*.

Furthermore, Applicant submits that the collected teachings of the cited references, *Dubief* and *Dalko*, do not suggest the evidence of unexpected results of tensioning effect described in the specification in Table 1. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Provisional Double Patenting Rejection

Finally, with respect to the provisional obviousness-type double patenting rejection of the present application on assertedly patentably indistinct claims of co-pending Application Serial Nos. 10/982,925 (the '925 Application), 10/508,007 (the '007 Application), 10/591,583 (the '583 Application) and 10/573,579 (the '579 Application), it is respectfully submitted that such rejection should be withdrawn. As stated in the M.P.E.P.:

If a provisional nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of

the two pending applications . . . the Examiner should withdraw that rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer.

M.P.E.P. § 804(1)(b)(i).

The present application was filed in 2003, and hence is an "earlier filed" application with respect to all of the cited applications since the '925 Application was filed on November 8, 2004; the '007 Application was filed on June 10, 2005; the '583 Application was filed on September 5, 2006, and the '579 Application was filed on December 26, 2006.

As it is believed that all of the rejections set forth in the Final Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 7, 2008

Respectfully submitted,

By 

Kelly Y. Hwang

Registration No.: 51,831

LERNER, DAVID, LITTENBERG,

KRUMHOLZ & MENTLIK, LLP

600 South Avenue West

Westfield, New Jersey 07090

(908) 654-5000

Attorney for Applicant